MB 1531

DEPARTMENT OF HEALTH & HUMAN SERVICES

11/15/99 RDB

Certified/Return Receipt Requested

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

November 12, 1999

WARNING LETTER

Leo Rutten, President/Owner
Hiawatha Milling Company
105 North Mill
Beloit, KS 67420

KAN #2000-003

Dear Mr. Rutten:

Recently an inspection was made of your medicated feed mill operation located at 706 South 10th Street, Hiawatha, Kansas. This inspection was conducted on September 2, 1999, by an inspector with the Kansas Department of Agriculture, who documented deviations from Current Good Manufacturing Practice (CGMP) Regulations for Medicated Feeds (21 CFR, Part 225). Such deviations cause the medicated feeds manufactured at this facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (Act).

Observations include, but are not limited to the following: 1) failure to include drug expiration dates in the drug inventory record; 2) failure to make a daily drug inventory as drugs are used; 3) failure to account for adjustments in drug inventories; 4) failure to have the Master Record signed or initialed by a qualified person; 5) failure to have proofread Master Labels initialed and dated; 6) failure of the Production Records to be signed or initialed as required.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. We are enclosing a copy of the Form FDA 483 that was issued to Bob Bloodworth, Mill Manager, at the conclusion of the inspection.

You should take prompt action to correct the noted violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory and/or administrative sanctions. These sanctions include, but are not limited to, seizure, injunction, and/or notice of opportunity for a hearing on a proposal to withdraw approval of your license, under Section 512(m)(4)(B)(ii) of the Act and 21 CFR 514.115(c)(2). (This letter constitutes official notification under the law.)

CRR:jl

Based on the results of the September 2 inspection, evaluated together with the evidence before FDA when your license was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of medicated feeds are inadequate to assure and preserve the identity, strength, quality, and purity of the new animal drugs therein. This letter notifies you of our findings and provides you an opportunity to correct the above deficiencies.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problems. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction.

Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

W. Michael Rogers
District Director
Kansas City District

Enclosure - Form FDA 483